20 March 2019

SUBMISSION OF VIEWS BY BRAZIL

NOTIFICATION CBD 2019-009
Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety

1. Introduction

In Decision CP-9/13, the Conference of the Parties serving as the meeting to the Parties to the Cartagena Protocol on Biosafety decided to establish a process for the identification and prioritization of specific issues regarding risk assessment of living modified organisms. In that sense, it also established an Ad Hoc Technical Expert Group on Risk Assessment and extended the online forum on risk assessment and risk management.

Brazil would like to stress that all discussions that occur during this process must attain themselves to the criteria set out in Annex I of Decision CP 9/13.

2. Information related to the risk assessment of living modified organisms containing engineered gene drives and living modified fish;

a) Experience in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish (detailing how and for which cases); or else, lack of experience in doing so;

In Brazil there are no specific guidelines for risk assessment of living modified fish. Like the other Modified Living Organisms (LMOs) a request for risk assessment of live modified fish must be submitted to the National Biosafety Technical Commission (CTNBio) which will make the risk assessment case-bycase, considering the particularities of each case, and based on scientific evidence.

Organisms containing engineered gene drives, or Gene Drive Organisms (GDOs) are covered by an specific normative for risk assessment described in Normative Resolution Nº16 of the CTNBio (RN16), which also include so-called New Breeding Technologies (NBTs). In cases that intend to use GDOs the request should be made to CTNBio which will evaluate whether GDOSs are considered as LMOs, what are the necessary risk assessment measures, and whether additional information and measures would be required.

However, it is necessary to empathize that no application regarding the use of GDO has been submitted to CTNBio until the present moment and therefore Brazil does not have any case of organisms containing engineered gene drives.

b) Challengers experienced or foreseen in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish;

Only one application for contained environment tests for genetically modified fish was submitted to CTNBio so far and the current general evaluation procedures were considered applicable and sufficient.

No request for the evaluation of living modified organisms containing engineered gene drives has been submitted to CTNBio, so far.

c) Specific needs (if any) to properly undertake risk assessment of living modified organisms containing engineered gene drives.

All initial evaluations of organisms containing engineered gene drives should be conducted in a containment environment. And, due to the nature and purpose of the technology that can alter, suppress or even eliminate a wild population, and also impact the chain related to this wild population, any kind of unintended release needs to be avoided, with special attention to the preliminar phases of the research. And therefore appropriate means must be used for containment and control measures. Therefore, control measures need to be proportional to the estimated risks in case of accidental release of organisms containing engineered gene drives into the environment [1]

In the early stages of research it is recommended that measures be taken whenever possible that prevent the GDOs from surviving in the environment and also prevent transmission of the cassette containing the drive gene.

The risk assessment should be performed to identify the containment and control needs to prevent unintended release and potential impact on the environment [1]. It is important to emphasize that the same principles of risk assessment used for LMOs can be used for living modified organisms containing engineered gene drives, especially the risk assessment protocols used for microorganisms that have the capacity to impact human, animal, plant and environmental health, asfor instance, the European Union's Directive on the contained use of genetically modified microorganisms[1] [2]

Based on the importance of new GMO microorganisms related to many different applications, such as cellulose production, second-generation ethanolic fermentation and vaccines, CTNBio published recently a normative to evaluate risk assessment for commercial use and release of GMO microorganisms and derivatives, called Normative Resolution nº 21, published in June, 15th 2018.

It will always be necessary to consider in the risk assessment the potential positive and negative impacts when using living modified organisms containing engineered gene drives. One of the most promising uses of gene drive is the reduction and population control of disease and pest vectors. In examples of arboviruses such as malaria it would be possible to reduce the 200 million infected people and cause half a million deaths annually [3] [4]

Besides that, a group of scientists and regulators came recently to the conclusion that gene drives when applied to Anopheles gambiae in an African environment for population substitution or population reduction, do not pose important risks either to the environment or to human health using the regular approach for GMO risk assessment [5].

References:

1 - A Framework for the Risk Assessment and Management of Gene Drive

Technology in Contained Use. Cécile J. B. van der Vlugt et al. Applied Biosafety:

Journal of ABSA International 23(1). 2018.

2 - Directive 2009/41/EC of the European Parliament and of the Council of 6 May

2009 on the contained use of genetically modified micro-organisms. 2009.

3 - Gene drive research: why it matters. The Royal Society. November, 2018.

4 - World Malaria Report. World Health Organisation (2015).

5 - Results from the workshop “Problem formulation for the use of gene drive in

mosquitoes”. Roberts A, Andrade PP, Okumu F, Quemada H, Savadogo M,

Singh JA, et al. Am J Trop Med Hyg. (2017).